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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,205	01/12/2001	Ralf Zielenski	RDID0013US	2666

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EXAMINER

CHAUDHRY, MAHREEN F

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 12/14/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/760,205	ZIELENSKI, RALF
<b>Examiner</b>	<b>Art Unit</b>	
Mahreen Chaudhry	1623	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 18-45 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 18-45 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites the limitation "the analyte" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 18-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,424,204 issued to Aoyama et al. Aoyama et al. disclose an assay reagent for determining the concentration of glucose, the concentration of a coenzyme or for measuring the activity of glucose-related enzyme (Column 5, Lines 56+). The reagent comprises a glucose 6-phosphate dehydrogenase and a stabilizer such as a hydroxylamine derivative (Column 5, Lines 59-66).

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Aoyama et al. disclose that the hydroxylamine is included in the solution in amount between 0.001 to 1 mol/l (Column 6, Lines 35-41). Aoyama et al. disclose that the reagent may additionally comprise a coenzyme such as NAD and NADP and a buffer including citrate and borate buffers (Column 6, Lines 12+). Aoyama et al. teach that a buffer may be included at a concentration between 0.005 to 2 mol/l and such that the pH is between 3 and 11 (Column 6, Lines 28-34). Aoyama et al. further teach that the amount of NADPH formed is measured by determining the change in absorbance at 340 nm (Column 8, Lines 4-9).

Aoyama et al. does not provide a specific example of a solution containing glucose 6-phosphate dehydrogenase and a hydroxylamine derivative in addition to a citrate or borate buffer. However, Aoyama et al. do teach an aqueous reagent comprising glucose 6-phosphate dehydrogenase and a hydroxylamine derivative and teach that the dehydrogenase and the hydroxylamine may be included in buffer solutions selected from citrate and borate buffers (Column 6, Lines 28+). It would therefore have been obvious to one having ordinary skill in the art at the time of the invention to have prepared an aqueous reagent including a dehydrogenase enzyme, a coenzyme and hydroxylamine as a stabilizer in buffer solution and to have utilized the solution for determining glucose concentration, for determining coenzyme concentration or for measuring the catalytic activity of an enzyme according to the specific teachings of Aoyama et al. It would additionally have been obvious to one having ordinary skill in the art to have prepared kits including an enzyme, a coenzyme, a hydroxylamine and an appropriate buffer as specifically taught by Aoyama et al.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent 5,036,000 issued to Palmer et al. discloses that O-substituted hydroxylamines may be included into aqueous solutions comprising NAD(P) and dehydrogenase in order to immobilize the oxidized substrate.

U.S. Patent 5,783,382 issued to Aoyama et al. discloses a method of storing a diagnostic reagent comprising an enzyme, an indicator and a coenzyme with a disoxidant such as a hydroxylamine derivative.

U.S. Patent 5,334,508 issued to Hoenes discloses a method for determining the concentration of an analyte by enzymatic oxidation in the presence of an electron acceptor such a hydroxylamine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mahreen Chaudhry whose telephone number is (703) 605-1200. The examiner can normally be reached on Monday – Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701 . The official fax phone number for the organization where this application is proceeding or assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

mc  
December 4, 2001

*R. Gitomer*  
RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200